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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,465	06/22/2001	Edward B. Nelson	MCP-267	6932

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EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/13/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/887,465	Nelson et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 27, 2003*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above, claim(s) *20-22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-19, 23, and 24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment filed May 27, 2003 has been received and entered into the file.

Applicant's arguments filed May 27, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 1-24 are presented for examination.

Applicant's election with traverse of Group I, directed to methods for treating atherosclerotic conditions` in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the number of species is limited. This is not found persuasive because the restriction was based on the distinction between methods of use and compositions of matter. .

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-22 reading on compositions of matter are withdrawn from consideration. Examiner apologizes for the inadvertent inclusion of claim 20 in the method of use group, this claim is directed to a composition of matter and thus, would be non-elected as not reading on the elected subject matter.

This application contains claims 19-22 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines antioxidants useful for treating coronary artery disease. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of antioxidant examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all antioxidant compounds, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

In the instant case, Applicants place an undue quantity of experimentation on the skilled artisan. To practice the invention as claimed the skilled artisan must undertake experimentation to ascertain if compounds identified in the prior art as antioxidant compounds suitable for practicing the invention as claimed. In the instant specification Applicants failed to provide any direction or guidance as to what criteria the skilled artisan would employ to ascertain those antioxidants possessing the required therapeutic properties. The anti-atherosclerotic prior art teaches treatment of the claimed conditions as unpredictable, thus, failing to provide proper guidance for the skilled artisan.

Additionally, Applicant fails to set forth the treatment regimens providing prevention of arteriosclerosis, or regression of arteriosclerosis. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these therapeutic regimens without undue experimentation. Applicants provide no prevention of arteriosclerosis, or regression of arteriosclerosis, examples thereby failing to provide sufficient working examples. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on complete prevention of arteriosclerosis, or regression, or cure, of arteriosclerosis situations neither illustrated, or discussed in the instant specification. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 23-24 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-2, 10-11, 23 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Winokur in view of Mitchelll et al.

Winokur teaches COX-2 inhibitors as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating arteriosclerosis, viewed by the skilled artisan as the condition herein claimed. Claims 1-2, 10-11, 23 and 24, and the primary references, differ as to:

1) the failure to recite the specific COX-2 inhibitor as useful for the anti-atherosclerotic use herein claimed.

This failure is cured by Mitchell et al teaching the claimed acetaminophen as an old and well known inhibitor of cyclooxygenase enzymes, specifically COX-2. Possessing these teachings the skilled artisan would have been motivated to employ the COX-2 inhibitors taught by Mitchell et al for the instant use and have enjoyed a reasonable expectation of therapeutic success.

Claims 11 and 24 specifically require a defined dose. Winokur teaches employment of Cox-2 inhibitors, at a rate not exceeding 50 mg/kg, meeting the instant dosage rate. The skilled artisan would have seen all conventional compositions, and

the administration of these compositions by conventional means, at conventional physiological dosages, as residing in the skilled artisan purview.

Claims 3-9 and 12-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Winokur in view of Mitchell et al as set forth for claims 1-2, 10-11, 23 and 24 above, in further view of Morehouse, Pick et al and Sun et al

Morehouse, Pick et al and Sun et al teach the acetaminophen, atorvastatin (claim 18), aspirin, vitamin C and vitamin E respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating arteriosclerosis, viewed by the skilled artisan as the condition herein claimed. Claims 3-9 and 12-18, and the primary references, differ as to:

1) the concomitant employment of these medicaments.

It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-atherosclerosis agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

RESPONSE TO ARGUMENTS

Newly presented obviousness rejections are necessitated by the declaration filed under 37 CFR 1.131. The newly presented obviousness rejection renders those rebuttal arguments directed to the previously presented obviousness rejection moot.

Examiner notes the exemplified anti-oxidants fail to provide guidance with regard to that class of compounds envisioned by Applicants. Absent guidance directing the skilled artisan to that class of compounds useful for practicing the invention as claimed the instant claims remain properly rejected as not enabled under 35 USC 112, first paragraph.

Examiner notes the instant claims read on prevention, yet those rebuttal arguments herein presented fail to support this utility. At page 8 of paper 12, Applicants set forth data residing in the instant specification. Attention is directed to the phrase "significantly reduced fatty streak deposits", setting forth a reduction in arteriosclerotic plaque formation, yet falling short of illustrating **prevention** of arteriosclerotic plaque formation herein envisioned and claimed. Simply stated, the instant specification fails to place the skilled artisan on possession of that regimen required to prevent the conditions herein envisioned, and claimed. Although the

claimed subject matter may provide prophylactic benefits, the prevention benefit herein claimed is not illustrated, or suggested, in the instant application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617